UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/675,828	09/29/2000	Thomas J. Cummins	CDS-266	1041

7590 12/05/2001

Philip S. Johnson, Esq.
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003

EXAMINER	
STRZELECKA, TERESA E	

ART UNIT	PAPER NUMBER
1656	9

DATE MAILED: 12/05/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/675,828	CUMMINS ET AL.	
	Examiner	Art Unit	
	Teresa E Strzelecka	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2001 and 11 November 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28,29,33 and 36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28,29,33 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group V, claims 28, 29, 33-35 in Paper No. 7 is acknowledged. Claims 1-14, 30-32 and 35 were cancelled. Subsequently, in an amendment filed on November 16, 2001 Applicants cancelled claim 34 and added new claim 36. Therefore, claims pending in the Application are: 28, 29, 33 and 36.

Priority

2. If applicant desires priority under 35 U.S.C. 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No._____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

No reference is made to the parent application, 08/062,023.

Oath/Declaration

3. There is no reference to the priority application in the Declaration.

Amendments

4. Preliminary Amendment filed on September 29, 2000 was typed too close to the top edge of the pages. As a result, holes were punched through the text. Most of the claims were cancelled, but claim 33 remained, and line 35 has gaps in the text.

Specification

5. The Brief Description of Drawings does not contain separate descriptions of Figures 1-6 and 9 and 10.

6. Sequence listing submitted with the application contains hand-written corrections on the first page which were not initialed.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claim 33 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,174,668. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between claim 7 of the '668 patent and claim 33 is the limitation of carrying out the PCR reaction for 20-50 cycles in claim 7, which makes claim 7 a species of claim 33.

Claim 1 of the '668 patent:

1. A method for the simultaneous amplification and detection of a first target DNA and a second target DNA comprising:

A) simultaneously subjecting the denatured opposing strands of a first target DNA and the denatured opposing strands of a second target DNA to polymerase chain reaction in the presence of:

i) an aqueous composition buffered to a pH of from 7 to 9, and comprising, in the same solution:

first and second primers which are specific to and hybridizable with, respectively, first and second nucleic acid sequences which are in opposing strands of a first target DNA and which are separated from each other along said opposing strands by from 90 to 400 nucleotides,

third and fourth primers which are specific to and hybridizable with, respectively, third and fourth nucleic acid sequences which are in opposing strands of a second target DNA which is the same as or different from said first target DNA, said third and fourth nucleic acid sequences being different from said first and second nucleic acid sequences and being separated from each other along said opposing strands of said second target DNA by from 90 to 400 nucleotides,

each of said first, second, third and fourth primers having a T_m within the range of from 65 to 74° C., all of said primer T_m's being within about 5° C. of each other, said first and second primers having nucleotide lengths which differ from each other by no more than 5 nucleotides, and said third and fourth primers having nucleotide lengths which differ from, each other by no more than 5 nucleotides, and

ii) the additional PCR reagents: a thermostable DNA polymerase, a DNA polymerase cofactor and dNTP's, any or all of said additional PCR reagents being supplied in the same

or a different composition as defined in i), to simultaneously amplify said opposing first target DNA strands and said opposing second target DNA strands,

B) simultaneously detecting at least one of said amplified first target DNA strands and at least one of said amplified second target DNA strands as a simultaneous determination of the presence of said first and second target DNA's.

Claim 6 of the '668 patent:

6. The method of claim 1 wherein PCR is carried out for from 20 to 50 cycles.

Claim 7 of the '668 patent:

7. The method of claim 6 wherein, in each PCR cycle, priming and primer extension are carried out at the same temperature within the range of from 62 to 75° C.

9. Claim 28 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,174,668. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to use the method of claim 7 to amplify more than two target DNAs.

10. Claim 29 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7 and 8 of U.S. Patent No. 6,174,668. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to use the method of claims 7 and 8 to amplify and detect more than two target DNAs.

11. Claim 36 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2 and 7 of U.S. Patent No. 6,174,668. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between claims 2 and 7 of the '668 patent and claim 36 are the limitation of

carrying out the PCR reaction for 20-50 cycles and the primers being 20-40 nucleotides in length, which makes claims 2 and 7 of the '668 patent species of claim 36.

Claim 1 of the '668 patent:

1. A method for the simultaneous amplification and detection of a first target DNA and a second target DNA comprising:

A) simultaneously subjecting the denatured opposing strands of a first target DNA and the denatured opposing strands of a second target DNA to polymerase chain reaction in the presence of:

i) an aqueous composition buffered to a pH of from 7 to 9, and comprising, in the same solution:

first and second primers which are specific to and hybridizable with, respectively, first and second nucleic acid sequences which are in opposing strands of a first target DNA and which are separated from each other along said opposing strands by from 90 to 400 nucleotides,

third and fourth primers which are specific to and hybridizable with, respectively, third and fourth nucleic acid sequences which are in opposing strands of a second target DNA which is the same as or different from said first target DNA, said third and fourth nucleic acid sequences being different from said first and second nucleic acid sequences and being separated from each other along said opposing strands of said second target DNA by from 90 to 400 nucleotides,

each of said first, second, third and fourth primers having a T_m within the range of from 65 to 74° C., all of said primer T_m 's being within about 5° C. of each other, said first and second primers having nucleotide lengths which differ from each other by

no more than 5 nucleotides, and said third and fourth primers having nucleotide lengths which differ from, each other by no more than 5 nucleotides, and

ii) the additional PCR reagents: a thermostable DNA polymerase, a DNA polymerase cofactor and dNTP's, any or all of said additional PCR reagents being supplied in the same or a different composition as defined in i), to simultaneously amplify said opposing first target DNA strands and said opposing second target DNA strands,

B) simultaneously detecting at least one of said amplified first target DNA strands and at least one of said amplified second target DNA strands as a simultaneous determination of the presence of said first and second target DNA's.

Claim 2 of the '668 patent:

2. . The method of claim 1 wherein each of said first, second, third and fourth primers has from 20 to 40 nucleotides, and a T_m within the range of from 67 to 74° C., said primer T_m 's being within about 2° C. of each other.

Claim 6 of the '668 patent:

6. The method of claim 1 wherein PCR is carried out for from 20 to 50 cycles.

Claim 7 of the '668 patent:

7. The method of claim 6 wherein, in each PCR cycle, priming and primer extension are carried out at the same temperature within the range of from 62 to 75° C.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 33, 28, 29 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The preamble to claims 33 and 36 states "A method for the simultaneous amplification and detection of a first target DNA and a second target DNA...", with the final method step being "...simultaneously detecting at least one of said amplified first target DNA strands and at least one of said amplified second target DNA strands as a simultaneous determination of the presence of said first and second target DNAs".

It is unclear whether "simultaneous" refers to simultaneous amplification and detection of the two targets or to amplification of two targets at the same time followed by detection of two targets at the same time.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

15. Claims 33, 28 and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Picone et al. (u.S. patent No. 5,614,388).

Picone et al. teach nucleic acid primers and probes for amplification of select target regions of Legionella genome. The multiple primer pairs can be used to amplify sequences of the 5S RNA and mip genes of multiple Legionella species (col. 2, lines 18-36). The amplification products are detected using multiple probes immobilized on solid support,

such as nylon, plastics, glass (col. 4, lines 18-27; col. 8, lines 20-23). There are two primer pairs for amplification of the mip gene with T_ms of about 65° C and eight primer pairs for amplification of the 5S RNA gene, T_ms of about 68° C. The length of primers ranges from 18 to 24 base pairs (col. 11, lines 45-55, Table 2). The detection probes are 17 to 25 base pairs long and have T_ms from 62 to 69° C, as calculated by the formula $T_m = 67.5 + 0.34(\%G+C) - 395/N$.

The isolated Legionella genomic DNA is amplified using PCR with primers for mip and 5S RNA genes in the same amplification mix, containing PCR buffer of pH 8.9, thermostable Taq DNA polymerase and dNTPs. The cycling conditions: 95° C for 1 minute, 63° C for 1.5 minutes, 72° C for 7 minutes (col. 16, lines 64-67; col. 17, lines 1-13, 34-36, 64-67; col. 18, lines 1-10). Simultaneous detection of PCR products is achieved either by gel electrophoresis (col. 18, lines 65-67; col. 19, lines 1-13) or by capture on nylon-immobilized capture probes at 50-55° C for 20 minutes (col. 19, lines 14-38; col. 20, lines 1-38).

16. No references were found teaching or anticipating claim 36, but it is rejected for other reasons.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (703) 306-5877. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at (703) 308-1152. The fax phone numbers for the organization

where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

TS
December 3, 2001 TS

Kenneth R. Horlick, Ph.D.
KENNETH R. HORLICK
PRIMARY EXAMINER
GROUP 1600
12/3/01